K000433

MEDICAL DEVICE TECHNOLOGIES INC

3600 SW 47th Avenue
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

JUN 1 6 2000

510(k) SUMMARY

APPLICANT:	Medical Device Technologies, Inc. 3600 SW 47th Avenue Gainesville, FL 32608
CONTACT:	Karl Swartz Quality Assurance Manager
TELEPHONE:	(352)338-0440 fax (352)338-0662
TRADE NAMES:	PBN Hystero-Salpingography Catheter
COMMON NAME:	Hystero-Salpingography catheter
CLASSIFICATION NAME:	Cannula, Manipulator/Injector, Uterine

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Ackrad Laboratories	H/S Catheter Set	K953034

DESCRIPTION OF DEVICE:

The PBN Hystero-Salpingography Catheter is comprised of a balloon bearing catheter, and a syringe to inflate the balloon.

The catheter material will be available in sizes ranging from 5 fr. to 7 fr., and is extruded from a flexible plastic tube, that is 30 to 40 cm in length. The distal end will have an end port. The balloon which is composed of a synthetic elastomer of a natural, clear kraton material is mounted 3 to 5 mm proximal to the distal end. The proximal end of the catheter is composed of a Y fitting leading to a stopcock for contrast media on one leg of the Y fitting, and a stopcock for inflating the balloon on the other leg of the Y fitting.

The syringe is a 5 cc size. The syringe has a vent at the 2.5 cc graduation providing that volume for inflation of the 5 fr. Balloon. The recommended volume for the 7 fr. Balloon is 3.0 cc.

INDICATIONS FOR USE:

The PBN Hystero-Salpingography Catheters are intended for use in the injection of contrast material in the examination of the uterus and fallopian tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2000

Mr. Karl Swartz
Quality Manager
Medical Device Technologies, Inc.
3600 SW 47th Avenue
Gainesville, FL 32608

Re: K000433
PBN Hystero-Salpingography Catheters
Dated: April 28, 2000
Received: May 1, 2000
Unclassified
Procode: 85 LKF

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

MEDICAL DEVICE TECHNOLOGIES INC
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Gainesville, Florida 32608
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510(k) Number (if known): K000433

Device Name: PBN Hystero-Salpingography Catheters

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000433